fully satisfactory, a high recurrence rate is observed and prevention strategies are not available. HPV vaccination studies have shown high efficacy against HPV-induced lesions such as GW. Before implementing a vaccination programme, data on the incidence and prevalence of GW and their associated treatment costs are crucial. The objective of this study was to estimate these data. **METHODS:** 217 specialists (gynecologists, urologists and dermatologists) were asked to record the number of patients, aged 14–64 yrs, presenting with GW between February and April 2005. The average number of patients per specialist was used to estimate the annual number of patients. Specialists also conducted a chart review of 189 previously diagnosed GW patients visiting them in the same period. Resource use, collected from records going back to February 2004, included visits, diagnostics, medications, procedures and adverse events. The cost of treating patients with an existing GW diagnosis was calculated using the average cost per patient and the extrapolated annual number of existing patients. Indirect costs were included. **RESULTS:** It was estimated that there are around 57,000 new cases and 38,000 existing cases of GW annually in Germany. Mean treatment duration was 6.7 months, with an average of 3.2 visits to a specialist. 95% of patients had a visual exam, and the most used diagnostics included Pap smears (25.9%), biopsies (25.4%) and colposcopies (24.9%). Most common therapies were imiquimod (34.4%), electrosurgery (26.5%), laser therapy (19.1%) and cryotherapy (17.5%). The mean annual treatment cost per existing patient was €950. The overall estimated treatment costs were €36 million per year; of which €7 million indirect costs. **CONCLUSION:** The management of GW presents a high burden to society that could potentially be reduced using a quadrivalent HPV vaccine.

METHODS & CONCEPTS

PMC1

DEVELOPMENT OF A NEW QUESTIONNAIRE TO MEASURE SATISFACTION WITH TREATMENT WITH MEDICINES (SATMED-Q)

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OBJECTIVE: New advances in health care have shifted concern from infectious to chronic illnesses and therefore a new emphasis in the assessment of satisfaction with pharmacological treatment has risen. A new generic questionnaire to measure Satisfaction with medicines is under construction. Item reduction and factorial validity are discussed here. **METHODS:** The initial instrument was composed by 36 items, arranged in 6 dimensions: 1- Efficacy and symptom relieve (5 items), 2- Ease and convenience (6 items), 3- Impact on HRQoL (4 items), 4- Satisfaction with Medical Care (4 items), 5- Medication Side Effects (8 items), and 6- Overall satisfaction (9 items). Items and dimensions where extracted from review of previous English instruments, a panel compose by 8 experts, and 4 focus groups with chronic patients. A convenience sample of 156 patients was used, representative of 7 prevalent chronic pathologies (Diabetes type II, Hypertension, Osteoarthritis, Prostate problems, EPOC/Asthma, Depression, and Migraine). Classic psychometric theory item analysis techniques, exploratory factor analysis, and confirmatory factor analysis (to estimate accurately factor correlations) were applied. **RESULTS:** The questionnaire was reduced to a new version of 5 dimensions assessed by 14 items, plus a dimension of Satisfaction with Medication Side Effects (3 items) to be corrected separately due to an important floor effect. The reduced version presents an overall Cronbach alpha of 0.881, acceptable goodness of fit indexes, and all factor loadings are significant ($p < 0.001$). Dimensions are well formed and correlate in different degrees, but the dimension of Satisfaction with Medical Care shows a relevant relation only with Impact on HRQoL ($r = 0.45$). **CONCLUSION:** The questionnaire shows good reliability and validity properties. The 5 + 1 proposed dimensions are stable and well defined in a 17-item form. Results support that the questionnaire can be used to compute an overall meaningful score.

PMC2

REVIEW OF THE ACTIVITIES OF THE ISOQOL TRANSLATION AND CULTURAL ADAPTATION (TCA) SPECIAL INTEREST GROUP (SIG)

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The special interest group (SIG) on Translation and Cultural Adaptation (TCA) had its first meeting in Hong Kong at the 2004 Annual ISOQOL meeting. The overall objective of the TCA SIG is to identify and advance research in different areas of interest to all parties involved in the field of Translation and Cultural Adaptation. Three priority areas of research were identified and organised in three subgroups: translation difficulties, equivalences and methodologies. **OBJECTIVES:** The objectives of subgroup one are: 1. To collect, review and analyse examples of translations difficulties in the adaptation of Patient-Reported Outcomes (PRO) measures; 2. To create a list of "good practices" for developers of questionnaires and translators, based on the review of common translation difficulties and proposed solutions on how to prevent them. **METHODS:** The group has organised its activities in 4 steps: 1. Categorisation of difficulties; 2. Collection of examples of translation difficulties; 3. Review of examples; and 4. Recommendations. **RESULTS:** Translation difficulties were divided into categories according to: 1. Their position within the PRO questionnaire (i.e. Demographics, levels of education, "race", Instructions, Items and Response Choices); 2.The layout used, e.g. e-layout, tables, font-related problems; and 3. Their nature: Cultural (Is the construct to be measured relevant in the target cultures?); Conceptual and Semantic (Do the items represent the construct definition?); Syntactic; and Idiomatic. Examples of translation difficulties for each category defined previously and for a selection of families and branches of languages have been collected and will be presented. Recommendations on how to prevent potential translation difficulties will be proposed to developers of PRO questionnaires. **CONCLUSIONS:** The translation of PRO measures is a difficult task. "Good practices" for the development and translation of PRO measures should be implemented to facilitate the use of linguistically valid PRO measures in international research.

PMC3

INTERNATIONAL VARIATION IN CLINICAL INJURY INCIDENCE: REAL OR ARTIFICIAL DIFFERENCES?

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OBJECTIVES: To analyse variation in clinical injury incidence of 7 European countries, and to determine whether using different injury indicators can minimize the bias in clinical injury incidence data and increase the comparability of the data.